

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended): An apparatus for attaching respective tube segments of a series of tube segments to respective ones of a series of flexible bags by fusing them together to form a series of sterilized flexible packages and filling the series of flexible packages with a product, said apparatus comprising a totally aseptic environment providing in an aseptic form, fill and seal operation in said totally aseptic environment, the series of flexible bags being formed of a web of film and being releasably interconnected to one another, each of the series of flexible bags comprising wall portions defining a hollow interior space and a pair of opposing peripheral edge portions confronting each other to define an a first interface space in communication with the hollow interior space, each of the tube segments being an elongated member having an opposed pair of ends, a passageway interconnecting the ends and an exterior surface, one of the ends being open and the other of the ends being closed, said totally aseptic environment of said apparatus comprising:

means for forming the series of bags from the web of film, whereupon each of the bags comprises a second interface space between opposing wall portions of the bag and with the second interface space being in communication with the hollow interior space;

a sterile processing chamber including means for receiving adapted to receive the series of sterilized tube segments and the series of flexible bags to sterilize the series of flexible bags

a tube inserter at least partially located within said processing chamber, said tube inserter comprising means and arranged to grip respective ones of the series of sterilized tube segments and place the respective ones of the sterilized tube segments in the first interface space between the opposing sterilized peripheral edge portions of respective ones of the flexible bags in the said sterile processing chamber;

~~at least one member~~ means for fusing ~~the~~ a portion of the exterior surface of each respective one of the sterilized tube segments between the opposing sterilized peripheral edge portions of the respective ones of the sterilized flexible bags so that the open end of a respective one of the tube segments is in communication with the interior space in a respective one of the sterilized flexible bags and the closed end of each of a respective one of the sterilized tube segments is located outside of a respective one of the sterilized flexible bags; and

means for filling the hollow interior of each of the sterilized flexible packages with the product through the second interface space; and then

means for sealing the packages with the product therein.

Claim 2 (original): The apparatus of claim 1, further comprising: a tube sterilization chamber in which tubing from a supply of tubing is introduced, the tube sterilization chamber being in communication with the sterile processing chamber.

Claim 3 (original): The apparatus of claim 2, wherein the tube sterilization chamber includes a hydrogen peroxide bath.

Claim 4 (original): The apparatus of claim 3, further comprising a dryer located downstream of the bath.

Claim 5 (original): The apparatus of claim 4, wherein the dryer comprises a heated sterile air supply.

Claim 6 (original): The apparatus of claim 3, further comprising a plurality of rollers located in the bath, the tubing extending between the rollers to provide a desired dwell time to ensure sterility.

Claim 7 (original): The apparatus of claim 2, wherein the tube sterilization chamber is at least one of a hydrogen peroxide vapor chamber, a hydrogen peroxide bath, an ultraviolet radiation chamber, an ion radiation chamber, or a high intensity pulsed light chamber.

Claim 8 (original): The apparatus of claim 1, further comprising a hydrogen peroxide vapor generator connected to the sterile processing chamber that feeds hydrogen peroxide vapor into the chamber.

Claim 9 (original): The apparatus of claim 8, wherein the hydrogen peroxide vapor is at least at a 31% concentration.

Claim 10 (original): The apparatus of claim 1, further comprising a tube supply unwind stand with a supply of tubing.

Claim 11 (original): The apparatus of claim 1, wherein the unwind stand includes a brake to keep tension on the tubing.

Claim 12 (original): The apparatus of claim 10, wherein the supply of tubing includes pre-crimped, irradiated tubing so that an inside of the tubing is sterile.

Claim 13 (original): The apparatus of claim 10, wherein supply of tubing comprises tubing crimped only at each end, the apparatus further comprising at least one pre-heat section to preheat a portion of the tubing, and a crimper located downstream of the preheater to crimp the tubing into sealed tube segments.

Claim 14 (original): The apparatus of claim 10, further comprising: a cutter located in a sterile area in or in communication with the sterile processing chamber to cut the tube segment from the supply of tubing.

Claim 15 (original): The apparatus of claim 14, wherein the tube cutter comprises opposing blades that are driven together to cut the tubing into tube segments.

Claim 16 (original): The apparatus of claim 15, wherein the opposing blades mounted to at least one rotary actuator, swing toward one another to cut the tubing.

Claim 17 (original): The apparatus of claim 14, wherein the supply of tubing is pre-crimped, and the apparatus further comprises a crimp position sensor in proximity to the tube cutter, the crimp position sensor being adapted to detect a position of the crimp to allow a location of cut to be positioned adjacent to the crimp.

Claim 18 (original): The apparatus of claim 14, wherein the tube cutter is mounted for movement by an actuator to adjust a position of the tube cutter based on a crimp in the tubing.

Claim 19 (original): The apparatus of claim 14, wherein the cutter is preheated.

Claim 20 (original): The apparatus of claim 10, further comprising opposing drive wheels to grip and pull the tubing from the supply of tubing.

Claim 21 (original): the apparatus of claim 20, further comprising a dancing bar located in a path of the tubing, the dancing bar is moveable between upper and lower positions, and a sensor connected to the dancing bar which signals the drive wheels to feed additional tubing when the dancing bar approaches the upper position.

Claim 22 (original): The apparatus of claim 10, wherein the inserter comprises opposing jaws that are moveable toward one another to grip an end of tubing from the supply of tubing prior to the tubing being cut from the supply of tubing to form the tube segment.

Claim 23 (original): The apparatus of claim 22, wherein the opposing jaws are moveable toward and away from the bag film.

Claim 24 (original): The apparatus of claim 23, wherein the opposing jaws are moved linearly by linear actuators connected to the jaws to insert the open end of the tube segment between the sides of the bag film.

Claim 25 (currently amended): The apparatus of claim 1, further comprising a film splitter that separates the opposing peripheral edge portions of respective bags from one another at a tube insertion site prior to the inserter placing the tube segment in position.

Claim 26 (previously amended): The apparatus of claim 25, wherein the film splitter comprises two arms joined in a V-shaped arrangement that moves from a first position, in which only a first part of the arms at a base of the V are located between the opposing peripheral edge portions so that the peripheral edge portions are not separated, to a second position, in which spaced apart ends of the arms are moved between and separate the peripheral edge portions to allow insertion of the tube segment therebetween.

Claim 27 (original): The apparatus of claim 1, wherein ~~the at least one member~~ means

for fusing is arranged to provide ultrasonic energy to the open end of the tube located between the wall portions of said bag.

Claim 28 (currently amended): the apparatus of claim 1, wherein the ~~at least one member~~ means for fusing comprises at least one sealing jaw for heat sealing the open end of the tube segment between the peripheral edge portions.

Claim 29 (original): The apparatus of claim 28, wherein there are two opposed heat sealing jaws which include a recess complementary to and smaller than a diameter of the tube segment.

Claim 30 (original): The apparatus of claim 29, wherein the heat sealing jaws include a fin seal for an edge of the bag.

Claim 31 (previously amended): The apparatus of claim 30, wherein the heat sealing jaws each include a plurality of heating zones that are controlled independently to provide a different heat sealing temperature in an area of a seal between the wall portions to form the edge seam than an area of a seal between the peripheral edge portions and the tube segment.

Claim 32 (currently amended): The apparatus of claim 31, wherein the heat sealing jaws are arranged to be heated to 350-450. degree. F. for heat sealing the peripheral edge portions to the tube segments, and from 250-350.degree. F. for heat sealing the wall portions together to form the edge seam.

Claim 33 (previously amended): The apparatus of claim 29, wherein the heat sealing jaws are movable from a first, non-contact position, away from the walls of the bag, to a second, sealing position, in contact with the walls of the bag, to seal the tube segment between the peripheral edge portions.

Claim 34 (original): The apparatus of claim 29, wherein the heat sealing jaws include a tube sealing recess with a flattened profile having a circumference that is smaller than a circumference of the tube segment.

Claim 35 (original): The apparatus of claim 29, further comprising a controller to control a tube cut position, a tube feed rate, a temperature of heat sealing jaws and a sealing tube.

Claim 36 (original): The apparatus of claim 1, wherein tubing from a tubing supply is introduced into the sterile processing chamber, the apparatus further comprising a pressure sensor to determine if a sterile environment in the sterile processing chamber is breached, and a tubing crimper which crimps the tubing upon the pressure sensor detecting a loss of pressurization to maintain sterility of the tube supply.

Claims 37 – 46: canceled.

Claim 47 (previously amended): A method of attaching respective tube segments of a series of tube segments to respective ones of a series of flexible bags by fusing them together to form a series of sterilized flexible packages and filling the series of flexible packages with a product in an aseptic form, fill and seal operation, comprising:

providing a web of film defining a series of flexible bags releasably interconnected to one another, each of the series of flexible bags comprising wall portions defining a hollow interior space and a pair of opposing peripheral edge portions confronting each other to define an interface space in communication with the hollow interior space;

sterilizing the series of flexible bags within a processing chamber;

providing a series of sterilized tube segments in the processing chamber, each of the sterilized tube segments having an exterior surface, an open end and a closed end;

inserting respective ones of the open ends of the sterilized tube segments between the opposing sterilized peripheral edge portions of respective ones of the flexible bags in the processing chamber;

fusing a portion of the exterior surface of each respective one of the sterilized tube segments between the opposing sterilized peripheral edge portions of respective ones of the sterilized flexible bags so that a respective one of the open end of the tube segments is in communication with the interior space in a respective one of the sterilized flexible bags and the closed end of each of a respective one of the sterilized tube segments is located outside of a respective one of the sterilized flexible bags; and

filling the hollow interior of each of the sterilized flexible packages with the product and then sealing the packages with the product therein.

Claim 48 (previously amended): The method of claim 47, further comprising: feeding tubing through a sterilization area into a sterile environment; and cutting respective ones tube segments from a free end of the tubing to form said series of sterilized tube segments.

Claim 49 (original): The method of claim 48, further comprising: sterilizing an outside of the tubing in a hydrogen peroxide bath; and drying the tubing with a dryer located downstream of the bath.

Claim 50 (original): The method of claim 49, further comprising: feeding the tubing through a plurality of rollers located in the bath to provide a desired dwell time to ensure sterility.

Claim 51 (original): The method of claim 48, further comprising: feeding hydrogen peroxide vapor into the sterilizing area to sterilize an outside of the tubing.

Claim 52 (original): The method of claim 48, further comprising: sterilizing an outside of the tubing using at least one of the hydrogen peroxide vapor chamber, a hydrogen peroxide bath, an ultraviolet radiation chamber, an ion radiation chamber, or a high intensity pulsed light chamber.

Claim 53 (original): The method of claim 48, further comprising: unwinding the tubing from a roll on an unwind stand; and applying tension to the tubing.

Claim 54 (original): The method of claim 48, further comprising: supplying the tubing with a plurality of evenly spaced apart crimps, such that the tubing includes a plurality of sealed, sterile inner segments.

Claim 55 (original): The method of claim 48, further comprising: providing the tubing crimped only at each end and having a single sterile inner volume; preheating a portion of the tubing; and crimping an end segment of the tubing to form a separate, sealed tube segment.

Claim 56 (original): The method of claim 48, further comprising: preheating the cutter for cutting the tube segment.

Claim 57 (original): The method of claim 48, further comprising: supplying the tubing with a plurality of evenly spaced apart crimps, such that the tubing includes a plurality of sealed, sterile inner segments; sensing a position of a crimp for the last tubing segment; adjusting a location of the cut so that the tubing is cut adjacent to the crimp.

Claim 58 (original): The method of claim 48, further comprising: gripping and pulling the tubing from a tube supply using opposing drive wheels; sensing an amount of slack tubing using a dancing bar located along a path of the tubing; and feeding additional tubing when the dancing bar approaches an upper position.

Claim 59 (previously amended): The method of claim 48, wherein the method produces a plurality of flexible packages in sequence, the method further comprising: gripping a free end of the tubing with opposing gripper jaws prior to cutting the tube segment to be inserted into a next bag from the tubing.

Claim 60 (original): The method of claim 59, further comprising: linearly moving the opposing jaws with the tube segment toward the film.

Claim 61 (currently amended): The method of claim 47, further comprising: separating the opposing sterilized peripheral edge portions in an insertion area prior to insertion of a respective one of the tube segments therein.

Claim 62 (original): The method of claim 47, wherein the fusing takes place by heating sealing.

Claim 63 (original): The method of claim 62, wherein the step of heat sealing includes: providing heat sealing jaws with a recess complementary to and smaller than a diameter of the tube segment; pre-heating the heat sealing jaws; and moving the heat sealing jaws into contact

with the film from opposing sides with the tube segment located in a complementary position to the recess.

Claim 64 (previously amended): The method of claim 63, further comprising: forming a fin seal for an edge of the bag with the heat sealing jaws simultaneously with heat sealing the tube segment between the opposing sterilized peripheral edge portions.

Claim 65 (previously amended): The method of claim 63, further comprising: moving the heat sealing jaws from a first, non-contact position, away from the film, to a second, sealing position in contact with the film to seal the tube segment between the opposing sterilized peripheral edge portions; and moving the heat sealing jaws back to the first position to allow the bag to index forward to a next station.

Claim 66 (previously amended): The method of claim 47, further comprising: filling the flexible package with a viscous or semi-viscous product prior to sealing a final one of the edges.

Claim 67 (canceled).